REMARKS

Status of the Claims

Claims 76-92, 94-104, and 106-109 will be pending in the application upon entry of the present amendment. Claims 76-91 and 98-104 are currently withdrawn from consideration. Claims 92, 94-97, and 106-109 stand ready for further action on the merits. Claim 105 has been cancelled herein. Claim 92 has been amended to include the subject matter of claim 105. Support for the additional recitations to claim 92 can be found in the present specification, *inter alia*, at page 92, lines 9-34. Claims 107-109 have been added. Support for new claims 107-109 can be found in claim 92 as well as the present specification, *inter alia*, at page 1, lines 5-21. No new matter has been added. Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 92, 94-97, and 105-106 under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for the prevention of any gastrointestinal infections, does not provide enablement for the treatment of gastrointestinal bacterial infections caused by something other than *E. coli* and *zHelicobacter*, and does not provide enablement for the treatment of gastrointestinal viral or other parasitic infections. Applicants respectfully traverse.

The present invention is directed to the treatment, preventive treatment, and analysis of several types of pathogens and pathogen receptors in the human gastrointestinal tract. The present invention discloses combinations of pathogen adhesion activities and corresponding gastrointestinal receptors. As indicated by the Examiner, there are differences between pathogens. However, the present invention is broadly useful because the present invention discloses for the first time useful combinations of pathogen receptors. One of ordinary skill in the art would know that, despite their differences, all pathogen types, including bacteria, viruses, and parasites, need to attach to the same receptors since there is a limited amount of effectively useful attachment configurations in the target tissue, i.e., the gastrointestinal tract.

The glycomics analysis of the intestine revealed effective receptors available in the gastrointestinal tract for diarrheagenic pathogens, such as bacterial and viral pathogens. Various diarrheagenic *E. coli* and *zoonotic Helicobacter* species are quite different, but the adhesion activities are quite similar, indicating adaptation of the diarrhea pathogens to the intestinal niche. If these pathogens must use the same receptors, other pathogens must likely do the same since pathogenesis without binding to the host tissue is not possible.

In order to further prosecution, Applicants have also added independent claim 107, which mirrors claim 92 except limits the cause of the gastrointestinal infection to diarrhea-causing gastrointestinal pathogens. New claim 108 further limits the diarrhea-causing gastrointestinal pathogens to diarrhea-causing gastrointestinal bacterial pathogens, and new claim 109 further limits the diarrhea-causing gastrointestinal pathogens to *E. coli* and *zHelicobacter*. Applicants respectfully submit that claims 107-109 are allowable for the reasons recited herein. As such, Applicants respectfully assert that claims 107-109 clearly define over the prior art of record, and an early action to this effect is earnestly solicited.

Turning to the term "prophylactically," the Examiner gives the term an absolute meaning, which is not intended. Applicants respectfully submit that nothing occurs absolutely in biology. However, the present specification states, "The term 'treatment' used herein relates both to treatment in order to cure or alleviate a disease or a condition, and to treatment in order to prevent the development of a disease or a condition" (page 92, lines 31-34). Accordingly, claim 92 has been amended to delete the term "prophylactically" and now recites a method of "treatment in order to prevent the development of said infection." Applicants respectfully submit that this element is enabled by the present specification.

For the reasons given above in view of the amended claim 92, Applicants respectfully submit that the outstanding rejection has been overcome and should be removed.

Issues under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 92, 94-97, and 105-106 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner alleges that the limitation "a therapeutical composition containing purified fraction(s) of at least two compounds" is indefinite because "containing" is open language, which permits the inclusion of elements, such as impurities, other than purified fraction(s) in the composition. Applicants respectfully traverse in view of the amended claim.

Claim 92 has been amended to include the subject matter of claim 105 and further recites that the "composition is not human milk." Applicants respectfully assert that these additional elements further define the term "purified." For these reasons, Applicants respectfully submit that the outstanding rejection has been overcome and should be removed.

Issues under 35 U.S.C. § 102(b)

The Examiner has rejected claims 92, 94-97, and 105-106 under 35 U.S.C. § 102(b) as being anticipated by Pickering et al. (Infection 21 (1993) No. 6, pages 355-357). Claim 105 has been cancelled herein, which renders the rejection as to this claim moot. With respect to the remaining claims, Applicants respectfully assert that Pickering et al. do not disclose each and every aspect of, at least, independent claim 92, from which claims 94-97 and 106 depend.

The Examiner refers to Pickering et al. relating to protective actions of human milk. It is also true that human milk contains LnNT and Neu5Acα3Galβ4Glc. However, it is also known that human milk contains numerous active components. Pickering et al. do not refer to the specific saccharides. Furthermore, claim 92 has been amended to specifically exclude human milk, and the phrase "purified fraction(s)" is now further defined as "purified or isolated oligosaccharide fraction(s) from natural or synthetic sources." Therefore, the claims do not include the embodiment of human milk which is not a fractionated product.

Applicants respectfully submit that the analysis of Pickering et al. is based on retrospective consideration using the information derived from the present invention.

Applicants also traverse the interpretation that "the free LnNT and Neu5Acα3Galβ4Glc in human milk can be considered purified fractions within the milk composition." As discussed previously, natural human milk is a very complex mixture, and the effective active components in it cannot be known based on milk studies. Furthermore, human milk is not useful for production of regular infant formula due to the low amount of material available and potential infection risks.

Accordingly, the present invention is not anticipated by Pickering et al. since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Pickering et al. do not render the present invention obvious because neither the reference nor the knowledge in the art provides any disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed.

CONCLUSION

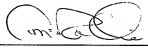
A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 92, 94-97, and 106-109 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: March 25, 2009

Respectfully submitted,

By 

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